

SIEMENS

ARCADIS Orbic

SP

DHHS Maintenance Instructions

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Text emphasis

DANGER

DANGER indicates when there is an immediate danger that leads to death or serious physical injury.

WARNING

WARNING indicates a risk of danger that may lead to death or serious physical injury.

CAUTION

CAUTION used with the safety alert symbol indicates a risk of danger that leads to slight or moderate physical injury and/or damage to property.

NOTICE

NOTICE used without the safety alert symbol indicates a risk of danger that if disregarded leads or may lead to a potential situation which may result in an undesirable result or state other than death, physical injury or property damage.

NOTE

NOTE contains information provided with special emphasis to facilitate proper use of the equipment or proper execution of a procedure, i.e. hints, tips.

Symbols



Checks and adjustments that must be performed with radiation ON are identified by the radiation warning symbol.

Safety information and protective measures

WARNING

Dangerous X-ray radiation during checks and maintenance work steps.

Risk of death or serious physical injury.

For checks and adjustments that must be performed with the radiation switched on, radiation safety measures must be observed.

- Use available radiation protection devices.
- Wear radiation protection clothing (lead apron)
- Stay as far away as possible from the radiation source.
- Release radiation only if necessary.
- Release radiation for as short a time as possible.
- Set the radiation activity as low as possible (low kV values, low mA values, short radiation time).

Checks requiring the release of radiation are identified by the radiation warning symbol as shown on the left.



WARNING

Risk of physical injury or death and property damage!

Noncompliance can lead to death, physical injury or property damage.

When performing the checks and maintenance work steps, please note:

- the product-specific safety information in this document,
- the safety information in the register Safety of the ARCADIS Operating Instructions.



Danger of pathogen infection!

Noncompliance can lead to death or physical injury.

- **This product is released for use in operating rooms and can be contaminated with infectious blood or other body secretions.**
- **Avoid all contact with blood or other body secretions!**

To ensure compliance with the applicable provisions of the Federal Performance Standard, the user of the equipment has to ensure that the maintenance procedure described below is performed at intervals of six months or less. In case the user does not comply with these requirements, the manufacturer can no longer be held liable.

If the results of any of the tests described in this document exceed the tolerances given, the required adjustments must be performed.

Contact Siemens service.

After performing any adjustment, all applicable tests must be repeated.

Customer:	Customer No.:	Room:
BZ-No.:	Type No.:	Serial No.:

After completion of maintenance:

I hereby certify that all procedures described in these maintenance instructions have been completed as specified and that the tolerance values are within the accepted range.

Date

Signature

1 Required reference documents

- DHHS Test certificate 1a+ and Acceptance Test Protocol (in Register 3 of the Logbook)

2 Required test equipment

- PTW-Diados	Serial-No.:	Date of calibration
- Fluke	Serial-No.:	Date of calibration
- Calculator		

3 Safety Notes



All local safety regulations must be observed.

4 Notes for the Maintenance Instructions

- Compliance with the applicable sections of the Federal Performance Standards is assured when all procedures described in these instructions have been performed and tolerance values are within the specified range.
- The unit movements required for these procedures must be performed cautiously to prevent the unit from being damaged in the event of a malfunction.



Checks or adjustments to be performed with radiation ON are marked with the radiation warning symbol

- When performing safety checks or adjustments with radiation ON, radiation protection clothing must be worn.

4.1 Calibration of the Integrated Dose Measurement Device option

A calibration of the optional installed Integrated dose measurement device (air kerma measurement device or area dose product measurement device) is not necessary.

4.2 Information about air kerma strength determination

The air kerma strength is determined with a measuring chamber integrated into the system. The reference location for determining the air kerma strength is 30 cm in front of the image intensifier input.



This value is used because in typical applications the object to be examined is located approx. 30cm in front of the I.I.

These assumptions also apply for ARCADIS Orbic 3D, since this reference location is at a distance of 70cm from the focal spot (focal spot - I.I. = 100cm) and thus in the isocenter range (focal spot - isocenter = 63.4cm)

1 Radiation protection

Make sure that there is no mechanical damage on the SIREPHOS tube housing assembly and image intensifier which could impair the radiation protection.

SIREPHOS and image intensifier
have been checked for mechanical
damage

YES

NO

Damage present (brief description):

2 Checking the DHHS and Identification Labels

Confirm that the certification labels as well as serial number and model number labels are legible. Use the illustrations which are shown in the Operating Instructions of the product. If labels are required, contact the SIEMENS Medical Solutions Local Service Organization or the SIEMENS Medical Solutions Regulatory Affairs department.

Component certified	Model No.	Serial No.	Date
ARCADIS Orbic X-ray control			
Beam Limiting device BLD			
SIREPHOS Tube housing assembly			
Image Intensifier			
Warning label present and legible			<input type="checkbox"/> YES

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1 Checking the "deadman" switch function

1.2 Fluoroscopy



Activate fluoroscopy for a short time and release the fluoroscopy switch.
Fluoroscopy must stop immediately.

- a) with the fluoroscopic switch at the control console
- b) with the foot switch

Deadman's switch is functioning	<input type="checkbox"/> YES	<input type="checkbox"/> NO
---------------------------------	------------------------------	-----------------------------

2 Radiation indicators



Check that the radiation indicators at the control console and on the monitor cart are visible during radiation.

Radiation indicators are functioning	<input type="checkbox"/> YES	<input type="checkbox"/> NO
--------------------------------------	------------------------------	-----------------------------

3 Fluoroscopy timer

1. Ensure that the people present are not subject to radiation hazard during the tests described below.
2. Set the manual fluoroscopy voltage to the lowest possible kV value. Close the Iris diaphragm, cover the tube assembly with a lead apron.
3. Switch on fluoroscopy.
4. Check that the acoustic signal sounds after a total fluoroscopy time of 4.5 minutes has elapsed.
5. Reset the buzzer by pressing the button >0< on the operating panel.



Fluoroscopy timer functioning correctly	<input type="checkbox"/> YES	<input type="checkbox"/> NO
---	------------------------------	-----------------------------

4 Indication of X-ray tube voltage and current

Confirm that tube voltage and current are continuously indicated during fluoroscopy.

Indicators functioning	<input type="checkbox"/> YES	<input type="checkbox"/> NO
------------------------	------------------------------	-----------------------------

5 Minimum source to skin distance

Confirm that a spacer limiting the source to skin distance (SSD) to 30 cm is present.

Spacer present	<input type="checkbox"/> YES	<input type="checkbox"/> NO
----------------	------------------------------	-----------------------------

1 Checking the accuracy of the tube voltage

The actual kV value must agree with the indicated value within the limits stated by Siemens (max. deviation $\pm 10\%$ for the ARCADIS Orbic), if the X-ray system is connected to a power supply corresponding to Siemens specifications.

Tools: PTW-Nomex

Test procedure:

Refer to the information on the Nomex in the operating instructions

Connect the Nomex.

Remove the single-tank cap on the SIREPHOS after removing the two screws.

Select full image intensifier format and open the collimator fully.

Place the measuring detector on the diaphragm.

Set the following values in the operating field and check



Operating mode	Indicated	Measured	Tolerance
Fluoroscopy	70 kV		63 kV to 77 kV
Fluoroscopy	101 kV		91 kV to 110kV
Fluoroscopy	110 kV		100 kV to 120 kV
Radiography	102 kV		92 kV to 110kV

2 Reproducibility

The coefficient of variation must not exceed 0.05 when the X-ray system is connected to a power supply as specified by Siemens.

The technique factors should be adjusted to alternate settings and reset to the test setting after each measurement.

2.1 Measurement set-up

Place the dosimeter in the center of the X-ray beam.

Before each new dose measurement, make sure that the indicator is reset to zero.



2.2 Calculations

Variation coefficient C

For n individual measurements, the coefficient of variation C amounts to:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

s = calculated standard deviation

\bar{x} = mean value of all individual measurements

x_i = measured value of the ith measurements.

1. To obtain the average x, the 4 dose values are added and the sum is divided by 4.
2. To obtain the difference, the average value is subtracted from each individual measured value and entered into the column provided

Measurement	Radiation Exposure (x_i)	Average (\bar{x})	= Difference*
1			
2			
3			
4			

* Disregard the sign if negative numbers are obtained.

Square the differences

Measurement	Square of the difference ($x_i - \bar{x}$) ²
1	
2	
3	
4	

3. Add the 4 results: Σ
4. Divide the sum by 4:
5. Obtain the square root of the new result: Square root S:
6. Divide the square root S by the average value x determined in step 1:

$$\text{Coefficient of variation } C = \frac{S}{\bar{x}} \quad C = \dots \quad (\text{must be } \leq 0.05)$$

3 Entrance dose rate

The legal maximum entrance dose rate is 87 mGy/min (10 R/min).

For safety reasons, the value has been fixed at < 78 mGy/min (9 R/min) at the factory.

The entrance dose rate is to be checked by means of a dose rate meter.

In the measurement setup shown, the maximum adjustable values 110 kV yield an input dose rate of approx. 87mGy/min (10 R/min).

Measurement set-up

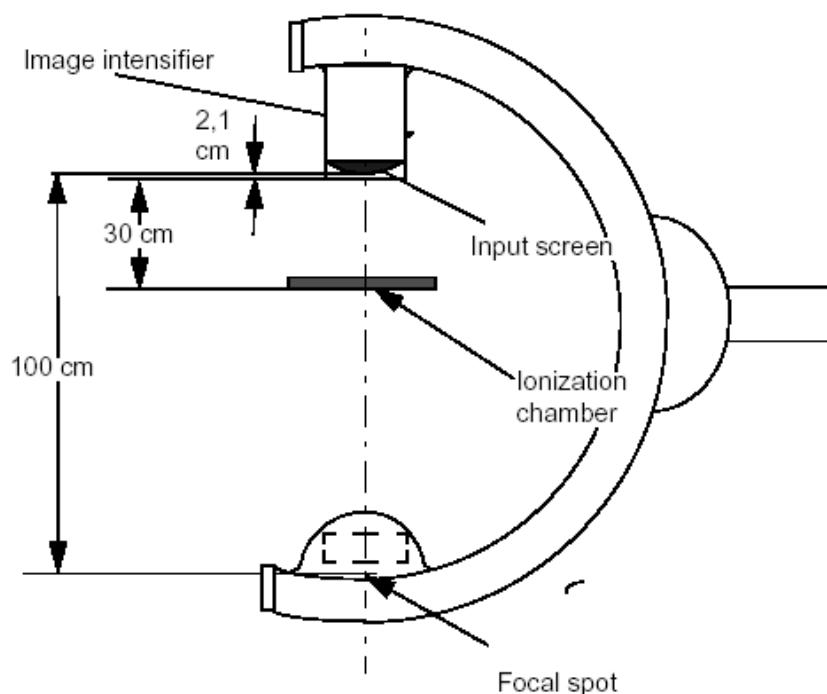


Fig. 1

Position the measurement detector of the dosimeter as shown in the diagram.

Press the "⊗" button at the operating console.

Select 110 kV. Select full I.I. format, open the collimator to max. aperture, switch fluoroscopy "ON". Measure the dose and record.



4 Check the I.I. format

Basic position

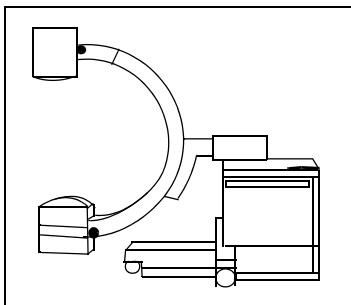
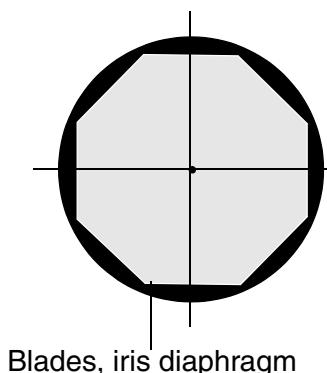


Fig. 2

TV image



Blades, iris diaphragm

Fig. 3

Work sequence:

1. Move the C-arm in the basic position.
2. Select the full I.I. input format.
3. Set the iris diaphragm to max. aperture
4. Switch on fluoroscopy
If all eight blades of the iris diaphragm are still visible at the edge of the TV monitor (Fig. 3), no further tests are necessary.
5. Select zoom format (check as in item 3).



I.I. format in order

YES

NO

Zoom format in order

YES

NO

5 Check the smallest field size

The smallest field size should be $< 5 \text{ cm} \times 5 \text{ cm}$ at the I.I. input.

The check is made at the TV monitor.

1. Select full I.I. view format.
2. Close the iris diaphragm and select full I.I. view format.
3. Attach a center cross with lead ruler to the center of the I.I. input screen.
4. Switch on fluoroscopy.
5. Read the size of the X iris on the monitor.



Smallest field size at the I.I. input: cm x cm

6 Check the field limitation

REGULATION -

Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors.

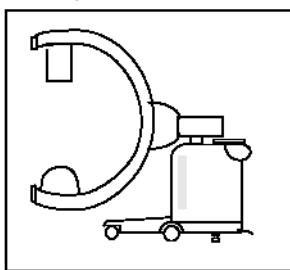
When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor.

The check is made at the TV monitor.

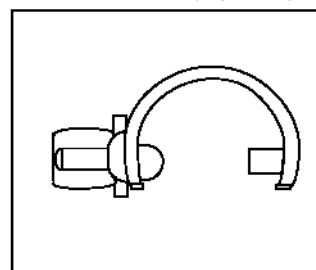
Determine the central point at the I.I. input. Use adhesive tape to attach center cross (with lead ruler).

Open the slot collimator, adjust the iris diaphragm to an opening of about 15 cm. Perform the test in the C-arm position shown.

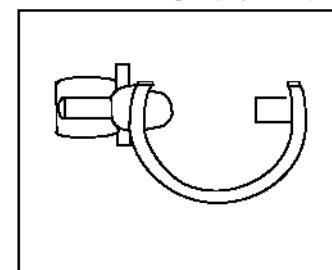
Basic position



C-arm to the left (top view)



C-arm to the right (top view)



SID (source image intensifier distance) = 100 cm

Fig. 4

A = mid-point I.I. input
 B = middle of the radiation field
 Δ = deviation of A to B
 x = deviation in the x-axis
 y = deviation in the y-axis

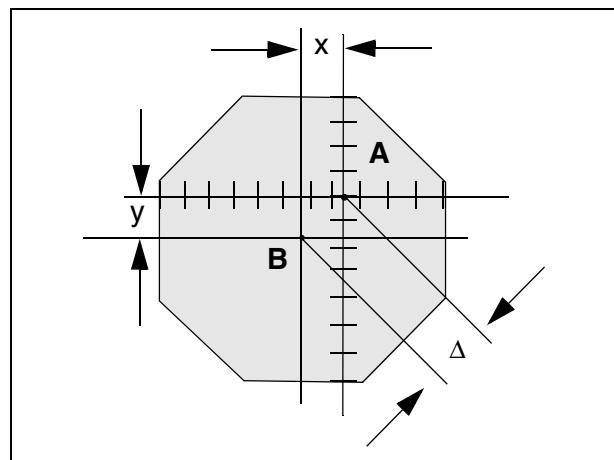


Fig. 5

Work sequence:

1. Select full size (no zoom).
2. Adjust the Iris diaphragm to an opening of about 15 cm.
3. Adjust C-arm (see Fig. 4).
4. Switch on fluoroscopy briefly.
5. Read the evaluation at the TV Monitor (Fig. 5).
(Use stored image).
6. Calculate the deviation

$$\Delta : \sqrt{x^2 + y^2}$$

7. Test results (see also Fig. 3):



Average deviation	Δ	permissible*	Average deviation	actual
Basic position	Δ	must be < 33 mm (equal to > 80% overlapping of the visible area) mm	
C-arm to the left	Δ	must be < 33 mm (equal to > 80% overlapping of the visible area) mm	
C-arm to the right	Δ	must be < 33 mm (equal to > 80% overlapping of the visible area) mm	

Technical data for DHHS components

In accordance with Federal Radiation Performance Standards 21 CFR Subchapter J Paragraph 1020.30 (h)

X-Ray Controls and Generators

Nominal line voltage:	Rated line voltage:	Line-voltage-regulation:	Maximum line current:
100 V	± 10%	11%	28 A
110 V	± 10%	9%	26 A
120 V	± 10%	8%	24 A
127 V	± 10%	7%	22 A
200 V	± 10%	7%	14 A
230 V	± 10%	5%	12 A
240 V	± 10%	5%	12 A

Technique factors for maximum line current:

110 kV_p tube voltage, 13 mA tube current

Generator ratings:

Fluoroscopy:	110 kV _p maximum voltage 15.2 mA maximum current
Pulsed Fluoroscopy:	110 kV _p maximum voltage 23.0 mA maximum current
Digital Radiography:	110 kV _p maximum voltage 23.0 mA maximum current
Digital Radiography (k=1): (Single Shot Mode)	110 kV _p maximum voltage 250 mA maximum current
Road Map:	110 kV _p maximum voltage 15.2 mA maximum current
Subtraction:	110 kV _p maximum voltage 15.2 mA maximum current
Radiography:	Duty cycle: 1:60 - 40 kV/20 mA - 110 kV/13 mA

Maximum deviations**Fluoroscopy**

Tube voltage:	± 10 %
Tube current:	± 8 % ± 0.1 mA
Fluoroscopy timer:	0 to 5 min.

Basic measurement used

Peak tube potential:	DIADOS (2 filter method)
Tube current:	by using RMS multimeter
mAs-product:	PTW-Nomex

Tube Housing Assemblies

Maximum rated peak tube potential:	110 kV _p
Leakage technique factors:	110 kV _p /5.0 mA
Minimum filtration permanently in the useful beam: obtained at:	≥ 3.1 mm Al equivalent 80 kV _p
Minimum filtration permanently in the useful beam: obtained at:	≥ 3.9 mm Al equivalent 110 kV _p

Cooling curves

Tube housing cooling curve:	See Operator Manual
Tube rating charts:	See Operator Manual

Definitions of the measurement bases of technique factors**Exposure time tube current product:**

Measured on the mA measuring pins D1.X39-D1.X40 (x97 opened) in the tube current circuit near ground with an mAs meter (PTW Nomex or equivalent).

Peak tube voltage:

Measurement of kVp in radiography and in fluoroscopy, using PTW-Nomex (2 filter method).

Tube current:

As measured on the mA measuring pins D1.X39-D1.X40 (x97 opened) in the tube current circuit near ground with an mA meter (FLUKE 8060 A or equivalent), minus the current flowing through the built-in high-voltage divider of 0.0025 mA/kV_p.

Final visual and function checks

- After completion of all required operations and checks, perform a visual and function check.

For example, ensure that

- moving parts are freely moving
- there is no danger of collision for moving parts
- safety distances are maintained
- all parts are properly secured
- there is no perceptible damage, etc.

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